

APR - 5 1994

K960804

Summary of Safety and Effectiveness

Device Name: Dahlberg Hearing Aid with multi-channel compression circuit

Device Type: CIC, ITC or ITE Hearing Aid

Classification: Air Conduction Hearing Aid (77ESD), Class I.

Intended Use: To amplify and transmit sound to the ear.

Substantially
Equivalent to: Dahlberg K-AMP hearing aids which were cleared for
distribution under document control number K954941.

Registration
Number: 2110592

Materials: The hearing aid shells will be manufactured from materials that
are commonly used in the industry.

Assembly: The hearing aid will be assembled utilizing similar assembly
practices as Dahlberg's current products.

Technical
Characteristics: Dahlberg utilizes the ANSI S3.22-1987 methodology to test and
obtain performance data for hearing aids.

Fit: Mild to severe as dictated by the individual users audiogram.

Power: Zinc-Air battery size dependent on hearing aid model.